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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ilan Shalev

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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,348

Applicant(s)

SHALEV, ILAN

Examiner

Bhisma Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 16-18, 25, 36-38, 40-43, 48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-24, 26-35, 39, 44-47, and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claim 50 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 50 is drawn to an apparatus having extensions which do not provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body channel. Claim 50 is therefore drawn to a nonelected species as the elected species (shown in Figures 2A, 2B, 2C, and 2D) has extensions which do provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body channel (line 28 of page 11 to line 20 of page 12).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 50 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

2. Claims 1-15, 19-24, 26-35, 39, 44-47, and 49 are objected to because of the following informalities: Claims 1 and 49 recite the limitations "said aperture" in lines 4-9 and "said extension" in lines 5-6. There is insufficient antecedent basis for these limitations in these claims. In claim 9, the use of "an impediment comprising body tissue" is confusing, as it is not clear if this impediment refers to the impediment mentioned in lines 6-7 of claim 1 or if the impediment of claim 9 is in addition to the

impediment of claim 1. It is suggested that the phrase "an impediment comprising body tissue" in claim 9 be replaced with "the impediment which comprises body tissue". In line 1 of claim 10, "said impediment" should be replaced with "the impediment" as parts of the body cannot be claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 49 is rejected under 35 U.S.C. 102(b) as being antedated by Kaplan et al (U.S. Patent No. 5,609,574). In Figures 1 and 1E, Kaplan et al show an apparatus or device comprising a hollow tube (20) with apertures (22 and 34) and extensions (28 and 32). The extension is operative in a deflated or first position and an inflated or second position. In the first position, the extension is near the aperture (22). In the second position, at least part of the extension extends away from the aperture. At least one aperture (22) is located on the hollow tube.

5. Claim 49 is rejected under 35 U.S.C. 102(e) as being antedated by Zadno-Azizi (U.S. Patent No. 6,958,059). In Figures 12 and 13, Zadno-Azizi shows an apparatus or

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device comprising a hollow tube (14, 420) with apertures (240, 460) and an extension (12, 422). The extension is operative in a deflated or first position and an inflated or second position. In the first position, the extension is near an aperture. In the second position, at least part of the extension extends away from the aperture. At least one aperture (22) is located on the hollow tube.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7, 9-15, 19, 21-24, 27-34, 39, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al (U.S. Patent No. 5,609,574). In Figures 1 and 1E, Kaplan et al show an apparatus or device comprising a hollow tube (20) with apertures (22 and 34), expandable resilient extensions (28 and 32), and an activating mechanism (40). The extension is operative in a deflated or first position and an inflated or second position by the manual activation of the activating mechanism. The activating mechanism includes a reservoir containing expansion fluid which is used to expand the extension. In the first position, the extension is near the aperture (22). In the second position, at least part of the extension extends away from the aperture. Figure 6 shows the hollow tubes with additional apertures (34). As to claims 5-7, 9, and 10, in Figures 8A, 8B, and 17A – 17D, an impediment (S) in the form of an aggregate of

solid material or inflamed body tissue which is located down flow from the hollow tube or at least partly within the hollow tube is shown. In lines 46-56 of column 13, Kaplan et al disclose that an agent or impediment may be located partly within the hollow tube. As to claims 11 and 12, Kaplan et al teach that the device may be left in a the patient's body between treatments (lines 1-10, column 17) and disclose the claimed structural elements of the device, thus, the device of Kaplan et al is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 21-24, Kaplan et al teach that the delivery of the fluid may be performed before, after, or during the inflation of the extension (lines 18-31, column 16). As to claim 27, the apertures in Figure 6 would be covered by the wall tissue of a patient's vein as the device is advanced in a deflated configuration through the narrow passages of the patient's body. As to claims 28-31, Kaplan et al disclose the tube comprising or having a material or fluid which is delivered into the particular portions of a patient's body which include fluids which are capable of preventing aggregation of solids, clot formation, body tissue inflammatory response, and bacteria colonization (see lines 53-67 of column 9 and lines 36-49 of column 11). As to claims 44 and 45, Kaplan et al teach that the device may be adapted for veins, arteries, and other locations in a patient's body and disclose the claimed structural elements of the device, thus, the device of Kaplan et al is capable of being adapted for an arm vein and fro an non-vein vessel. As to claims 46 and 47, at least a part of the extension is axially displaced when it is in the inflated position and at least a part of the extension is radially displaced when it is in the inflated position. Kaplan et al disclose the apparatus substantially as claimed. Even though Kaplan et al

disclose that the dimensions (such as length and diameter) of the hollow tube will be selected according to the intended use of the apparatus (lines 21-34 of column 12), Kaplan et al are silent on the specifics of the hollow tube being characterized by a length of not more than 10 cm. The instant disclosure describes the parameter of length as being merely preferable, and does not describe it contributing any unexpected results to the tube. As such, the parameter of length is deemed a matter of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Applicant should note that in line 28 of page 13 to line 2 of page 14 of Applicant's specification, the length of the hollow tube is disclosed as being less than 10 cm or as being greater than 10 cm (i.e., as calculated when the length of the portion of the hollow tube within the body is added to the length of the portion of the hollow tube that is outside of the body).

8. Claims 1, 3, 5-7, 9-15, 19-24, 26-35, 39, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zadno-Azizi (U.S. Patent No. 6,958,059). In Figures 12 and 13, Zadno-Azizi shows an apparatus or device comprising a hollow tube (14, 420) with apertures (240, 460), a resilient expandable extension (12, 422), and an activating mechanism. The extension is operative in a deflated or first position and an inflated or second position by the automatic activation of the activating mechanism (see lines 9-32 of column 6). The activation can also be considered to be partly manual (rotation of the knob). The activating mechanism includes a reservoir containing expansion fluid which is used to expand the extension. In the first position, the extension is near an aperture. In the second position, at least part of the extension

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extends away from the aperture. As to claims 5-7, 9, and 10, in Figures 9A and 9B, an impediment (S) in the form of an aggregate of solid material or inflamed body tissue which is located down flow from the hollow tube or at least partly within the hollow tube is shown. As to claims 11 and 12, Zadno-Azizi discloses the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 21-24, Zadno-Azizi discloses the claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being adapted such that delivery of the fluid may be performed before, after, or during the inflation of the extension. As to claim 26, in Figure 11B, Zadno-Azizi show an aperture (328) which is covered by the extension (318) in a first or deflated position. As to claim 27, the apertures in Figure 12 would be covered by the wall tissue of a patient's vein as the device is advanced in a deflated configuration through the narrow passages of the patient's body. As to claims 28-31, Zadno-Azizi discloses the tube comprising or having a material or fluid which is delivered into the particular portions of a patient's body which include fluids which are capable of preventing aggregation of solids, clot formation, body tissue inflammatory response, and bacteria colonization (see line 44 of column 13 to line 6 of column 14). As to claim 35, Zadno-Azizi teaches using an expansion fluid containing drugs which affect the formation of impediments (see lines 31-56 of column 13) and an expandable extension (422) which is permeable to the drugs (see line 44 of column 17 to line 22 of column 18). As to claims 44 and 45, Zadno-Azizi teaches that the device may be adapted for veins, arteries, and other locations in a patient's body and disclose the

claimed structural elements of the device, thus, the device of Zadno-Azizi is capable of being adapted for an arm vein and for a non-vein vessel. As to claims 46 and 47, at least a part of the extension is axially displaced when it is in the inflated position and at least a part of the extension is radially displaced when it is in the inflated position. Even though Zadno-Azizi discloses that the length of the hollow tube will be varied according to the intended use of the apparatus (lines 6-17 of column 7), Zadno-Azizi is silent on the specifics of the hollow tube being characterized by a length of not more than 10 cm. The instant disclosure describes the parameter of length as being merely preferable, and does not describe it contributing any unexpected results to the tube. As such, the parameter of length is deemed a matter of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Applicant should note that in line 28 of page 13 to line 2 of page 14 of Applicant's specification, the length of the hollow tube is disclosed as being less than 10 cm or as being greater than 10 cm (i.e., as calculated when the length of the portion of the hollow tube within the body is added to the length of the portion of the hollow tube that is outside of the body).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al in view of admitted prior art (admission). Kaplan et al disclose a device which is used in a patient's body and which is capable of dislodging an impediment. However, Kaplan et al are silent on the specifics of the impediment being a venous valve. Admission discloses numerous impediments or blockages which may be present in a patient's body including a vein valve, a regularly occurring part of the body's vein system, which

may block an aperture of a inserted catheter or tube (see lines 5-13 of page 2 of applicant's specification). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of Kaplan et al to dislodge or unblock a venous valve as taught by Admission as a venous valve is a well known form of blockage that can occur in the patient's body.

Response to Arguments

10. Applicant's arguments with respect to claims 1-15, 19-24, 26-35, 39, and 44-47 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

